

UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF DELAWARE

ABBOTT LABORATORIES,
an Illinois corporation,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC.,
a Delaware corporation,

Defendant.

Civil Action No. 07-250-***

**TEVA PHARMACEUTICALS USA, INC.'S
FIRST AMENDED ANSWER, DEFENSES, AND COUNTERCLAIM**

Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") responds to the numbered paragraphs of the Complaint filed by Plaintiff, Abbott Laboratories ("Abbott") as follows:

THE PARTIES

1. Upon information and belief, Teva USA admits the allegations in Paragraph 1 of the Complaint.
2. Teva USA admits the allegations in Paragraph 2 of the Complaint.

JURISDICTION AND VENUE

3. The Complaint purports to assert claims under the patent laws of the United States and, therefore, the allegations in Paragraph 3 of the Complaint are admitted.
4. Teva USA admits the allegations in Paragraph 4 of the Complaint.
5. Teva USA admits the allegations in Paragraph 5 of the Complaint.

FACTUAL BACKGROUND

The '953 Patent

6. Upon information and belief, Teva USA admits the allegations in Paragraph 6 of the Complaint.

7. Upon information and belief, Teva USA admits the allegations in Paragraph 7 of the Complaint.

8. Upon information and belief, Teva USA admits the allegations in Paragraph 8 of the Complaint.

9. Teva USA lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 9 of the Complaint and, therefore, denies the allegations in Paragraph 9.

10. Upon information and belief, Teva USA admits the allegations in Paragraph 10 of the Complaint.

Teva USA Notifies Abbott Regarding the Filing of ANDA No. 78-700

11. Teva USA admits it sent a notice to Abbott, dated March 20, 2007, as required by 21 U.S.C. § 355(j), and further states that the notice speaks for itself.

12. Teva USA admits that it attached to its March 20, 2007 notice its “Detailed Statement of the Factual and Legal Bases” (“Detailed Statement”) for its Paragraph IV Certification. Teva USA further states that its Detailed Statement speaks for itself.

13. Teva USA admits that it filed Abbreviated New Drug Application (“ANDA”) No. 78-700 with the FDA and further states that its ANDA speaks for itself.

COUNT I: PURPORTED INFRINGEMENT OF THE '953 PATENT

14. In response to Paragraph 14 of the Complaint, Teva USA incorporates by reference its response to Paragraphs 1 through 13 of the Complaint as if set forth fully within.

15. Paragraph 15 of the Complaint states a legal conclusion to which Teva USA is not required to respond.

16. Teva USA denies the allegations in Paragraph 16 of the Complaint.

17. Teva USA denies the allegations in Paragraph 17 of the Complaint.

18. All allegations not specifically admitted are denied.

PRAYER FOR RELIEF

Teva USA denies that Abbott is entitled to any of the relief sought in the prayer for relief.

AFFIRMATIVE DEFENSES

**FIRST DEFENSE
FAILURE TO STATE A CLAIM**

The Complaint fails to state a claim upon which relief can be granted.

**SECOND DEFENSE
NON-INFRINGEMENT**

Teva USA is not infringing, has not infringed, nor will infringe, either literally or under the doctrine of equivalents, any claim of the '953 patent. Teva USA is not inducing, has not induced, nor will induce the infringement, either literally or under the doctrine of equivalents, of any claim of the '953 patent. Furthermore, Teva USA is not contributorily infringing, has not contributorily infringed, nor will contributorily infringe the '953 patent.

COUNTERCLAIM

Pursuant to Federal Rule of Civil Procedure 13, Teva USA asserts the following counterclaim against Abbott, and in support thereof, alleges as follows:

THE PARTIES

1. Teva USA is a Delaware corporation, having its principal place of business at 1090 Horsham Rd., P.O. Box 1090, North Wales, Pennsylvania 19454.
2. Upon information and belief, and according to the Complaint, Abbott is an Illinois corporation, having its principal place of business at Abbott Park, Illinois 60064.

JURISDICTION AND VENUE

3. This counterclaim arises under the patent laws of the United States, Title 35, United States Code, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the food and drug laws of the United States, 21 U.S.C. § 355.
4. Jurisdiction in this Court is proper under 28 U.S.C. §§ 1331, 1332, 1338, 2201, and 2202, and the patent laws of the United States, Title 35, United States Code.
5. Venue in this Court is proper under 28 U.S.C. § 1391.

BACKGROUND FACTS

6. Teva USA reasserts and incorporates by reference the allegations contained in Paragraphs 1-5 of its Counterclaim.
7. Abbott holds an approved New Drug Application (“NDA”) from the FDA for a divalproex formulation that sells under the name DEPAKOTE® ER.
8. NDA holders or applicants are required to file with the FDA the patent number and expiration information for any patent that claims the drug that is the subject of the NDA and

any patent that claims a method of using the subject drug. These patents are then published in the FDA's Orange Book.

9. In connection with the NDA for DEPAKOTE® ER, Abbott has caused nine patents to be listed by the FDA in the Orange Book: United States Patent Nos. 4,913,906, 4,988,731, 5,212,326, 6,419,953, 6,511,678, 6,528,090, 6,528,091, 6,713,086, and 6,720,004 (the "Listed Patents").

10. On or about March 20, 2007, Teva USA gave notice to Abbott that it had filed ANDA No. 78-700 with the FDA, seeking the FDA's approval to manufacture, use, and sell its proposed divalproex sodium extended release tablets, equivalent to 500 mg valproic acid (hereinafter, "Teva USA's divalproex product"). Teva USA provided a Paragraph IV certification as to six of the Listed Patents: United States Patent Nos. 6,419,953, 6,511,678, 6,528,090, 6,528,091, 6,713,086, and 6,720,004 (the "Certified Patents"). Abbott brought suit against Teva asserting only one of the Certified Patents - the '953 patent.

11. Teva USA's divalproex product does not infringe any claim of the '953 patent.

COUNT I: DECLARATION OF NON-INFRINGEMENT OF THE '953 PATENT

12. Teva USA reasserts and incorporates by reference the allegations contained in Paragraphs 1-11 of its Counterclaim.

13. There is an actual, substantial, and continuing justiciable controversy between Teva USA and Abbott regarding the alleged infringement of the '953 patent.

14. Neither Teva USA's divalproex product nor any process nor method for making or using Teva USA's divalproex product is covered by any claim of the '953 patent.

15. Teva USA seeks, and is entitled to, a declaration that Teva USA's divalproex product does not infringe any claim of the '953 patent.

PRAYER FOR RELIEF

WHEREFORE, Teva USA respectfully requests that this Court enter a judgment and Order:

- a. dismissing the Complaint, and each and every claim for relief contained therein, with prejudice;
- b. declaring that Teva USA has not infringed any claim of the '953 patent directly, by inducement of infringement, or otherwise;
- c. declaring that this is an exceptional case under 35 U.S.C. § 285 and that Teva USA is entitled to recover its reasonable attorneys' fees and costs incurred in this action; and
- d. awarding Teva USA such other and further relief as the Court deems just and proper.

Dated: June 7, 2007

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CERTIFICATE OF SERVICE

I, Karen E. Keller, Esquire, hereby certify that on June 7, 2007, a true and correct copy of the foregoing document was electronically filed with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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Additionally, I hereby certify that on June 7, 2007, copies of the foregoing document were served via hand delivery on the above-listed counsel and on the following counsel as indicated:

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